

§ 17.126

and Tobacco Laboratory for transmittal to the regional director (compliance). The notice shall list the numbers of all formulas to be adopted and shall indicate the plant where each was originally approved and the plant(s) where each is to be adopted. Some evidence of the relationship between the plants involved in the adoption shall be attached to the notice. The notice shall be referenced in Part IV of the supporting data (ATF Form 5154.2) filed with the first claim relating to the adopted formula(s).

§ 17.126 Formulas for intermediate products.

(a) The manufacturer shall submit a formula on ATF Form 5154.1 to the Alcohol and Tobacco Laboratory for each self-manufactured ingredient made with taxpaid spirits and intended for the manufacturer's own use in nonbeverage products, unless the formula for any such ingredient is fully expressed as part of the approved formula for each nonbeverage product in which that ingredient is used, or unless the formula for the ingredient is contained in one of the pharmaceutical publications listed in § 17.132.

(b) Upon receipt of Form 5154.1 covering a self-manufactured ingredient made with taxpaid spirits, the formula shall be examined under § 17.131. If the formula is approved for drawback, the ingredient shall be treated as a finished nonbeverage product for purposes of this part, rather than as an intermediate product, notwithstanding its use by the manufacturer. (For example, see § 17.152(d).) If the formula is disapproved for drawback, the ingredient may be treated as an intermediate product in accordance with this part. Requirements pertaining to intermediate products are found in § 17.185(b).

(c) If there is a change in the composition of an intermediate product, the manufacturer shall submit an amended or revised formula, as provided in § 17.122.

§ 17.127 Self-manufactured ingredients treated optionally as unfinished nonbeverage products.

A self-manufactured ingredient made with taxpaid spirits, which otherwise

27 CFR Ch. I (4–1–00 Edition)

would be treated as an intermediate product, may instead be treated as an unfinished nonbeverage product, if the ingredient's formula is fully expressed as a part of the approved formula for the nonbeverage product in which the ingredient will be used. A manufacturer desiring to change the treatment of an ingredient from "intermediate product" to "unfinished nonbeverage product" (or vice versa) may do so by resubmitting the applicable formula(s) on ATF Form 5154.1. Requirements pertaining to unfinished nonbeverage products are found in § 17.185(c).

APPROVAL OF FORMULAS

§ 17.131 Formulas on ATF Form 5154.1.

Upon receipt by the Alcohol and Tobacco Laboratory, formulas on ATF Form 5154.1 shall be examined and, if found to be medicines, medicinal preparations, food products, flavors, flavoring extracts, or perfume which are unfit for beverage purposes and which otherwise meet the requirements of law and this part, they shall be approved for drawback. If the formulas do not meet the requirements of the law and regulations for drawback products, they shall be disapproved.

§ 17.132 U.S.P., N.F., and H.P.U.S. preparations.

(a) *General.* Except as otherwise provided by paragraph (b) of this section or by ATF ruling, formulas for compounds in which alcohol is a prescribed quantitative ingredient, which are stated in the current revisions or editions of the United States Pharmacopoeia (U.S.P.), the National Formulary (N.F.), or the Homeopathic Pharmacopoeia of the United States (H.P.U.S.), shall be considered as approved formulas and may be used as formulas for drawback products without the filing of ATF Form 5154.1.

(b) *Exceptions.* Alcohol (including dehydrated alcohol and dehydrated alcohol injection), U.S.P.; alcohol and dextrose injection, U.S.P.; and tincture of ginger, H.P.U.S., have been found to be fit for beverage use and are disapproved for drawback. All attenuations of other H.P.U.S. products diluted beyond one part in 10,000 ("4x") are also disapproved for drawback, unless the